IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CAROLYN R. CARTER, Plaintiff, **v.** **MEDTRONIC, INC., et al.,** Defendants.	**Case No. 2:18-cv-724** **Judge James L. Graham** **Magistrate Judge Chelsey M. Vascura**

OPINION AND ORDER

This matter is before the Court for consideration of the Motion for Summary Judgment filed by Defendants Medtronic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Logistics, LLC ("Defendants") seeking summary judgment on Plaintiff Carolyn Carter's six claims alleging: (1) manufacturing defect, (2) failure to warn, (3) negligence, (4) negligence per se, (5) breach of express warranty, and (6) spoliation of evidence. (Def.'s Mot. Summ. J., ECF No. 30.) For the reasons set forth below, the Court **GRANTS** Defendants' Motion for Summary Judgment.

I. BACKGROUND

Defendants manufacture the SynchroMed® II Infusion System at issue in this case. The SynchroMed® II Infusion System is a programmable medical device that treats certain medical conditions by delivering pain medication via an implanted pump and catheter directly to the intrathecal area where fluid flows around the spinal cord. (Johnson Decl. ¶ 4, ECF No. 30-1 at 817.) SynchroMed® II Infusion System devices are Class III, premarket approved devices, subject to the Food and Drug Administration's most rigorous standard for medical devices. (*Id.*); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

Class III medical devices are regulated under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. 21 U.S.C. § 360e. The FDA approves Class III medical devices recognizing that those devices may "present[] a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii). Once a Class III medical device receives FDA premarket approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The FDA also retains the authority to withdraw its approval should it deem the medical device unsafe or ineffective. 21 U.S.C. § 360e(e)(1).

Plaintiff suffers from chronic back pain resulting from failed back surgery syndrome. (ECF No. 30 at 964; Am. Compl. ¶¶ 10, 92, ECF No. 8 at 324, 348.) On May 18, 1998, Dr. Bruce Massau surgically implanted a SynchroMed® II Infusion System to relieve Plaintiff's pain. (ECF No. 8 at 348.)

In April 2001, Dr. Massau removed the first infusion pump and implanted a second pump. (*Id.*) This became a pattern which continued for several years. On April 25, 2012, Dr. Massau implanted a fifth pump, which met all FDA manufacturing and functional requirements for commercial release. (*Id.* at 350; Linnertz Decl. ¶ 25, ECF No. 30-2 at 899.) Plaintiff admits that each of her pumps and catheters initially functioned well, but she later experienced drug withdrawal symptoms with each new device. (ECF No. 35 at 1217.) Plaintiff further admits that in November 2015, she "began experiencing similar issues as the prior Medtronic Pumps." (*Id.*)

On June 22, 2016, Plaintiff was again admitted to the hospital for drug withdrawal symptoms due to an interruption to her drug delivery system. (Ex. 6, ECF No. 30-6 at 932.) Plaintiff consented to a rotor study to evaluate the fifth infusion pump's rotors. (*Id.*; Ex. 9, ECF

No. 30-9 at 943.) On June 23, 2016, Dr. Massau determined that the rotors were not functioning and discussed another pump replacement with Plaintiff. (Ex. 6, ECF No. 30-6 at 932.). Dr. Massau also discussed the proposed explant procedure with Plaintiff's husband and noted, "They will go to work on getting a new catheter and pump offered for her." (*Id.* at 933.)

On July 6, 2016, Plaintiff presented for a preoperative medical risk stratification consult prior to her July 13, 2016 explant procedure. (Ex. 10, ECF No. 30-10 at 945.) Plaintiff's July 6, 2016 medical record states, "It was determined that pain pump wasn't working 6/2016." (*Id.*)

On July 13, 2016, Plaintiff presented for the surgical removal of the fifth pump, but the procedure was halted due to an abnormal heart rhythm. (Ex. 7, ECF No. 30-7 at 935.) Dr. Massau's July 13, 2016 operative report states that his rotor study demonstrated that Plaintiff's drug delivery "system pump is now dead, i.e., it is nonfunctioning," and that Plaintiff consented to its removal on that date. (*Id.* at 936.) Plaintiff's July 15, 2016 discharge record also states, "Current pain pump defective." (*Id.* at 937.) On July 27, 2016, Dr. Massau removed Plaintiff's fifth pump. (Ex. 8, ECF No. 30-8 at 939.)

Plaintiff filed suit on July 23, 2018. Plaintiff's First Amended Complaint asserts six claims against Defendants alleging: (1) manufacturing defect, (2) failure to warn, (3) negligence, (4) negligence per se, (5) breach of express warranty, and (6) spoliation of evidence.

Plaintiff claims that her fifth replacement SynchroMed® II pump was defective and caused the narcotic withdrawal injury for which she now seeks recovery.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56, summary judgment is proper if the evidentiary material in the record shows that there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Courts consider the evidence in

the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor." *Quigley v. Tuong Vinh Thai*, 707 F.3d 675, 679 (6th Cir. 2013) (internal citation omitted) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986)). The critical question here is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986).

"The moving party has the initial burden of proving that no genuine issue of material fact exists, and the court must draw all reasonable inferences in the light most favorable to the nonmoving party." *Stansberry v. Air Wisconsin Airlines Corp.*, 651 F.3d 482, 486 (6th Cir. 2011) (internal quotations omitted). "Once the moving party meets its initial burden, the nonmovant must 'designate specific facts showing that there is a genuine issue for trial.'" *Kimble v. Wasylyshyn*, No. 10–3110, 2011 WL 4469612, at *3 (6th Cir. Sept. 28, 2011) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986)); *see also* Fed. R. Civ. P. 56(c) (requiring a party maintaining that a fact is genuinely disputed to "cit[e] to particular parts of materials in the record"). "The nonmovant must, however, do more than simply show that there is some metaphysical doubt as to the material facts. [T]here must be evidence upon which a reasonable jury could return a verdict in favor of the non-moving party to create a genuine dispute." *Lee v. Metro. Gov't of Nashville & Davidson Cnty.*, 432 F. App'x 435, 441 (6th Cir. 2011) (internal quotations and citations omitted). "When a motion for summary judgment is properly made and supported and the nonmoving party fails to respond with a showing sufficient to establish an essential element of its case, summary judgment is appropriate." *Stansberry*, 651 F.3d at 486 (citing *Celotex*, 477 U.S. at 322–23).

III. DISCUSSION

Defendants seek judgment in their favor on Plaintiff's claims of: (1) manufacturing defect, (2) failure to warn, (3) negligence, (4) negligence per se, (5) breach of express warranty, and (6) spoliation of evidence.

A. Abandonment of Claims

Defendants assert that Plaintiff fails to address their arguments concerning her failure to warn (Count 2), negligence per se (Count 4), and spoliation (Count 6) claims in her response to their motion for summary judgment and therefore abandons these claims. (ECF No. 36 at 1235–36.) Upon reading Plaintiff's response in opposition (ECF No. 35), the Court agrees that Plaintiff has failed to respond to Defendants' arguments concerning her failure to warn, negligence per se, and spoliation claims.

The Sixth Circuit's position on a plaintiff's abandonment of a claim is well established. "[A] plaintiff is deemed to have abandoned a claim when a plaintiff fails to address it in response to a motion for summary judgment." *Brown v. VHS of Mich., Inc.*, 545 F. App'x 368, 372 (6th Cir. 2013) (citing *Hicks v. Concorde Career Coll.*, 449 F. App'x 484, 487 (6th Cir. 2011) (holding that a district court properly declines to consider the merits of a claim when a plaintiff fails to address it in a response to a motion for summary judgment); *Clark v. City of Dublin*, 178 F. App'x 522, 524–25 (6th Cir. 2006) (recognizing that the failure to respond properly to motion for summary judgment arguments constitutes abandonment of a claim). As Plaintiff never addresses Defendants' arguments concerning her failure to warn, negligence per se, and spoliation claims in her response to their motion for summary judgment, she is deemed to have abandoned those

claims. Accordingly, Defendants are entitled to judgment as a matter of law on Plaintiff's failure to warn (Count 2), negligence per se (Count 4), and spoliation (Count 6) claims.

Plaintiff's remaining claims allege manufacturing defect (Count 1), negligence (Count 3), and breach of express warranty (Count 5).

B. The Ohio Product Liability Act

Plaintiff brings her claims for negligence (Count 3) and breach of express warranty (Count 5) under common law theories of liability. Defendants argue that these claims must be dismissed under the Ohio Product Liability Act ("OPLA"), because such claims are not cognizable under the OPLA.

The OPLA specifies as follows:

> "Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> (c) Any failure of that product to conform to any relevant representation or warranty.

Ohio Rev. Code § 2307.71(A)(13).

Ohio Rev. Code. § 2307.71(B) further conveys, "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability causes of action." In § 2307.71(B), the Ohio General Assembly clearly expressed its intent to eliminate "all common law product liability claims or causes of action." In this case, it is undisputed that Plaintiff's negligence

and breach of express warranty claims were not pled with reference to any applicable provision of OPLA.[1]

While Plaintiff agrees that the "OPLA is intended to abrogate all common-law product liability claims or causes of actions with respect to product liability claims," she submits that she asserts these claims under an implied warranty theory for economic damages only and cites a case from this Court for the proposition that such claims are permissible in conjunction with OPLA claims.[2] (ECF No. 12 at 677.) The Court finds this argument unavailing, as Count 5 of Plaintiff's Amended Complaint is clearly entitled "Breach of Express Warranty" (ECF No. 8 at 372), and the Amended Complaint contains no reference whatsoever to an implied warranty claim and seeks noneconomic damages for all of her claims, including her common law claims for negligence (Count 3) and breach of express warranty (Count 5). (Am. Compl. ¶¶ 178, 192, 206–207, 222–223, 237–238.)

These undisputed facts support the conclusion that Plaintiff's common law claims of negligence and breach of express warranty are abrogated by the OPLA and warrant dismissal.

C. Statute of Limitations

Defendants further submit that even if Plaintiff had properly pled all of her claims, they are time-barred under the applicable statute of limitations.

Under Ohio law, product liability claims alleging personal injury are governed by a two-year statute of limitations. Ohio Rev. Code § 2305.10(A). Ohio's discovery rule provides that the cause of action does not accrue until a plaintiff either knows or reasonably should have known that 1) he or she was injured and 2) that his or her injury was proximately caused by defendant's

[1] Plaintiff's manufacturing defect claim (Count 1) does allege a violation of the OPLA per Ohio Rev. Code § 2307.71 and is therefore properly pled.
[2] *Great N. Ins. Co. v. BMW of N. Am. LLC*, 84 F. Supp. 3d 630, 649 (S.D. Ohio 2015).

conduct. *O'Stricker v. Jim Walter Corp*., 4 Ohio St.3d 84, 447 N.E.2d 727 (1983). "The discovery rule seeks to redress the unconscionable result reached by a strict application of the limitations period to injured parties whose right to recovery can be barred by the statute of limitation before the party is even aware of an injury's existence." *Flynn v. Bd. of Trs.*, 2006-Ohio-6622, ¶ 8 (Ct. App.).

Defendants insist that Plaintiff's claims are barred by the statute of limitations, because she was well aware of the existence of her injury prior to the explant of her fifth pump and filed suit more than two years after consenting to its removal. Plaintiff argues that under the discovery rule, her claims were tolled until the July 27, 2016 explant procedure, because her doctor did not inform her of the allegedly defective pump beforehand. Even viewing the evidence in the light most favorable to Plaintiff, this argument falls short, as "the discovery rule generally applies in cases of latent injury and not in cases of possible latent defects." *Baxley v. Harley-Davidson Motor Co.*, 2007-Ohio-3678, ¶ 8, 172 Ohio App. 3d 517, 520, 875 N.E.2d 989, 991.

The undisputed record evidence overwhelmingly demonstrates that Plaintiff knew prior to her July 27, 2016 explant procedure that her drug withdrawal injury was attributed to the fifth pump. Plaintiff admits that she first experienced issues with the fifth pump as early as November 2015. Plaintiff's medical records show that on June 22, 2016, she complained of narcotic withdrawal symptoms due to an interruption in her infusion system and was admitted to the hospital. That same day, she consented to a rotor study to evaluate her pump.

On June 23, 2016, Dr. Massau determined the pump was nonfunctional and shared this news postoperatively with Plaintiff and her husband and discussed arrangements for a pump replacement. Not only was Plaintiff alerted to both her drug withdrawal injury and its cause on June 23, 2016, but her subsequent medical records dated July 6–13, 2016 include Dr. Massau's

professional opinion that the fifth pump was defective, and that Plaintiff consented to the defective pump's explant prior to July 27, 2016.

This is not a case of latent injury for which the discovery rule applies. Viewing the undisputed evidence in the light most favorable to Plaintiff, she was alerted to her injury no later than June 22, 2016 and learned of its proximate cause on June 23, 2016. More than two years later, Plaintiff filed her claims on July 23, 2018. The Court therefore concludes that Plaintiff's claims are barred by Ohio's two-year statute of limitations on product liability claims relating to physical injury.

D. Federal Preemption

Defendants further maintain that notwithstanding the untimeliness of Plaintiff's claims, her state law claims alleging manufacturing defect and negligence (Counts 1 and 3) are also preempted by the Medical Device Amendments.

The MDA contains an express preemption provision concerning state regulation of medical devices, which states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> 21 U.S.C. § 360k(a).

In *Riegel*, the Supreme Court determined that for state law claims concerning a Class III medical device to avoid preemption, they must be "premised on a violation of FDA regulations" relating to that device. 552 U.S. at 330.

In her response in opposition, Plaintiff states that her fifth SynchroMed® II pump was manufactured in violation of federal law, and her claims therefore evade federal preemption. (ECF

No. 30 at 1216.) Though she correctly identifies the narrow exception to preemption, Plaintiff's statement is unsupported by the record before the Court, as she fails to identify any evidence demonstrating that her device was not manufactured in accordance with FDA standards.

Instead, Plaintiff asks this Court to determine that the doctrine of *res ipsa loquitur* applies to her claims. "*Res ipsa loquitur* permits an inference of negligence when there can be no other explanation." *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008). This theory of liability is insufficient to survive summary judgment.

To avoid preemption, a plaintiff cannot solely rely on the device's malfunction and the doctrine of *res ipsa loquitur* to suggest that the "thing speaks for itself," but must show that a defendant "deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019) (collecting cases). Here, Plaintiff must offer evidence that Defendants violated an FDA requirement applicable to her fifth pump and "cannot simply point to the malfunction itself to prove that [her device was] not manufactured in accordance with FDA/PMA specifications." *Davenport v. Medtronic, Inc*., 302 F. Supp. 2d 419, 438 (E.D. Pa. 2004); *see also Weber*, 940 F.3d at 1111; *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 776 (3d Cir. 2018).

The undisputed record evidence demonstrates that Plaintiff's fifth pump was manufactured in accordance with its FDA-approved specifications, subjected to a series of quality assurance tests to ensure compliance with its premarket approval requirements, and contained no defects when Defendants released the device for sale. (Linnertz Decl. ¶¶ 14–27, ECF No. 30-2 at 896–99.) Plaintiff provides no evidence to counter Defendants' detailed showing. She fails to disclose any

expert testimony and cannot rely on her own affidavit, as she lacks personal knowledge of FDA regulatory matters.[3]

In sum, Plaintiff has failed to establish a genuine dispute of material fact that Defendants violated an FDA requirement, and her claims are therefore preempted by the MDA. As Plaintiff has produced no evidence from which a reasonable jury could find in her favor, summary judgment is warranted on her manufacturing defect and negligence claims (Counts 1 and 3).

IV. CONCLUSION

For the reasons stated above, Defendants' Motion for Summary Judgment (ECF No. 30) is therefore **GRANTED**. Accordingly, Plaintiff's claims are **DISMISSED WITH PREJUDICE**. Consequently, Defendants' Second Motion to Dismiss (ECF No. 9) is **DENIED** as moot. In light of the Court's ruling on the motion for summary judgment, Defendants' Motion to Strike Portions of Plaintiff's Affidavit (ECF No. 37) is also **DENIED** as moot.

The Clerk is instructed to enter final judgment in favor of Defendants on all of Plaintiff's claims.

IT IS SO ORDERED.

/s/ James L. Graham
JAMES L. GRAHAM
United States District Judge

DATE: May 11, 2020

[3] An affidavit presented in opposition to a motion for summary judgment "must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4); *Reddy v. Good Samaritan Hosp. & Health Ctr.*, 137 F. Supp. 2d 948, 954 (S.D. Ohio 2000).